

## Basic Premises for Discussion: Public Members on NIH Peer Review Panels

The information below is intended to help establish some baseline understandings and premises for a discussion about the characteristics and roles of public members in peer review.

### What kinds of reviews do public members participate in?

- Public members can give valuable input to the reviews of research proposals that involve human participants (human subjects) directly and/or involve the donation of biospecimens (varied types) from human participants.
- Public members typically do not participate in other categories of review, including basic research, unless the scientific review staff determines there is a specific reason to seek their input.

### What is the rationale for including public members on peer review panels?

- It is the responsibility of the Scientific Review Administrator (SRA) to assemble a peer review panel which includes all the expertise areas needed to provide a full and fair review of the applications being considered. For studies which require the participation of human subjects, one of the areas required is expertise about prospective study participants.
- Aspects of the application where the study participant expert can provide especially useful insights include: adequacy of the recruitment plan; relation of the study design and requirements to participant retention; adequacy of the human subjects protections and the consent forms describing them; representation of minority populations, women, and children; and related factors. (See roles below.)
- While the inclusion of public members on Institute and Center advisory councils is also important, it has very different value. By the time proposals with sufficiently positive priority scores reach the consideration of the council, the kinds of valuable and important contributions which public members can make earlier in the process are lost.
- Public members have been successfully incorporated into peer review panels at some NIH Institutes for years, with positive, value-added results.

### Who are “public members” for peer review panels?

- Public members are individuals who are qualified to represent the perspective of the participants who would need to be recruited and retained for the proposed research. This is a different perspective from that of scientific and related experts (statisticians, fiscal specialists, etc.) traditionally represented on peer review panels. The experience of Institutes which have included public members in peer review reflects an added dimension and value to the review.

- “Public members” are **not** simply members of the public. Public members could be patients currently or previously treated for the conditions being proposed for study, family members or other personal caretakers, or other individuals qualified to provide the needed perspective on the “community” of patients to be recruited and retained for the proposed research. Individuals qualified for review have specific experience, background, and expertise; are carefully selected through an application and review process; and receive training about the NIH peer review system and procedures.
- “Public members” is a generic term, still in development. Other labels used to identify reviewers from the public have included “patient representative”, “consumer advocate”, “patient advocate”, and others. However, reviewers are sometimes caretakers instead of patients (such as parents instead of children representing pediatric illnesses); and reviewers do not “advocate” in the commonly-understood way. Therefore, because a review panel has “members” and these come from the public, for the moment the generic term is “public member”.

### What is the role of public members in a peer review?

From their unique perspective (see above), public members participate in the scientific and technical evaluation of the proposals being considered in the peer review. Examples include:

- Whether the preventive, diagnostic, or treatment being proposed is something that individuals perceive to be worth participating in – and therefore is a study likely to be able to recruit participants.
- Whether the study is designed in a way that it is feasible for patients to participate (degree of pain or other side effects in the context of daily life; practicalities such as work schedules or transportation, etc.) – and therefore is a study likely to be able to retain participants.
- Whether the human subjects protection provisions are sufficient, and whether they are described adequately in the informed consent documents – and therefore participants will be protected from harm and sponsoring institutions are less likely to encounter avoidable adverse events and their consequences.
- Whether the study includes recruitment plans for minorities, women, and children (unless ruled out by the nature of the research itself), including populations with certain cultural beliefs which intersect with the research; and if so, whether the recruitment plans have taken all the important factors into account and provided for them – and therefore whether those targeted populations will, in fact, be recruited in sufficient numbers for the study.
- Whether the study addresses specific concerns, such as privacy issues – and therefore whether the participants’ privacy will be protected from exposure and the sponsoring institution will be less likely to encounter challenges to its procedures.

- Several other arenas, depending on the applications being considered – such as whether the proposed research will have a patient advisory group, whether the research team will have needed community support, whether necessary ancillary staff has been accounted for, etc. – and therefore whether the study is likely to be completed with as many enabling factors and as few complications as possible.

#### What roles do public members of a peer review NOT have?

- Public members do not evaluate a proposal based on their own personal disease or other experience, rather than the broad perspective of the “community” of people affected by that condition. (This includes not relating stories about one’s own personal experience.)
- Public members do not advocate for or against any topic, type, or scope of research.
- Public members do not advocate for their specific organizations or personal causes/biases.
- Public members do not question anything about the potential funding of this or related research.
- Public members do not become involved in the scientific or technical aspects of the review beyond the patient perspective (exceptions occur only if a member happens to be particularly qualified in a certain area and if that input is requested by the SRA or the panel).

#### To what extent are public members like all the other members on a peer review panel?

Public members in peer reviews are not expected to be scientists – any more than a statistician participating in a review is expected to review the use of proposed new medications, or a biochemist member of a panel is expected to review proposed surgical procedures. Public members have their own areas of expertise, just like each of the other members of the panel, and therefore can be considered “peers” in peer review. They are also treated as peers by the SRAs.

#### Public members for peer review:

- Are invited to participate by the SRA, who has determined – sometimes in collaboration with other scientific staff – that because the proposed research to be reviewed involves human participation, the inclusion of public members in the review will provide important value-added expertise.
- Disclose potential conflicts of interest by the same standards as the other peer reviewers.
- Are strictly bound by the rules of confidentiality, just as other members are.
- Follow all the instructions and deadlines of the SRA.

- Commit to devoting the necessary time and attention to training and to peer review tasks before, during, and after a peer review panel meeting.
- Follow all the protocols and practices of the review group, including being cognizant of the need to be concise and to function efficiently and effectively.
- Are treated with the same respect granted to other members.
- In most cases have a vote, just like other members who provide important expertise to the peer review panel.
- Have their travel and other appropriate expenses covered, like other members; and they receive an honorarium if other members do.

### In Summary

Institutes which have included public members in peer review for years continue to do so because it helps their review panels yield the best possible collaborative scientific and technical evaluation about research proposals. Including public members in peer review is a cost-efficient policy, especially important in resource-limited times. Public members often provide input and insight into proposals that end up saving taxpayer monies that would otherwise be spent on proposals which may be scientifically and technically excellent in theory but not in practice.